

Keys for reader response to written healthcare communication:

A contrastive study of English and translated German patient information leaflets (PILs)

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### Abstract

While earlier studies examined reader comprehension, this paper in the field of written healthcare communication focuses on potential reader response for original English and translated German patient information leaflets (PILs) and hence patient behaviour. For that purpose the cultural dimension of Uncertainty Avoidance (UA) as a measure of controlling future events following Hofstede (2001) was examined. Hofstede's study reveals a markedly higher UA index for Germany than for the UK. For this paper UA was defined in terms of analytical criteria which include aspects of epistemic and deontic modality, writer-reader relation and external role relation (ERRO), (causal) explication, as well as degrees of explicitness and subjectivity, and explicit uncertainty markers (EUMs). The translation corpus consists of two sections (one informative and one instructive) from 10 PILs (9, 659 words) for medicines treating hypertension and insomnia, taken from the European Medicines Agency (EMA). The findings show matching values for the analytical criteria in the English source text PILs and the German translated PILs to a considerable extent, albeit a higher frequency of explicit uncertainty markers and causal explication, and a somewhat higher degree of objectivity in the German PILs. These results, and the paucity of translation shifts for the analytical criteria, may, however, partly be attributed to close translation practice which otherwise transpires in literally translated, unidiomatic phrases in the German PILs. This may raise questions of suitability of translation practice for reader response and patient behaviour with written healthcare communication, notably also for texts in more culturally diverse language communities.

*Keywords:* medical translation, parallel corpora, Uncertainty Avoidance, modality

## **Introduction**

Today most patients expect shared decision-making (SDM), involving them in treatment decisions based on extensive information on their disease and the potential risks of therapeutic interventions. Awareness of therapeutic risks both on the side of clinicians and patients helps to avoid therapeutic mistakes and to improve therapeutic compliance, as numerous studies revealed (Nink & Schröder 2005, p. 19). In the transfer of information first of all clinicians and pharmacists are important actors, but patient information leaflets play an important role in this process as well. The relevance of patient information leaflets with regard to safety of drug use, patient behaviour, and public health should not be underestimated as they provide comprehensive information on medicines including possible side effects and risks. Patients rely on this information and thus can make informed decisions about the safe and effective use of the medicines they take. In view of the obvious relevance of patient information leaflets for patient information and guidance the question rises how factual information and instructions are expressed linguistically in these leaflets in order to enable patients to take their medication in a safe and effective way. For this purpose we focus on uncertainty avoidance in factual information and instructions or warnings, as expressed by the use of modals as well as other linguistic means in the communication of a medicine's use, potential risks and side effects from a cross-linguistic perspective (English and German). Before we start with this analysis, we first give some background information on the design and rationale of patient information leaflets.

### **Patient information leaflet: design and rationale**

Patient information leaflets represent a very common format of written health information and accompany all kinds of medicines on the market (both prescribed and over-the-counter (OTC) medicines). They are produced by pharmaceutical enterprises. Their design and content is regulated by the national and European legislations and supervised by national and supranational medicines agencies (such as the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) in Germany, the Medicines and Healthcare Products Regulatory Agency, MHRA in the UK, and the European Medicines Agency in the European Union). Since the early 1990s the medicines legislation is regulated at both the national and EU levels and patient information leaflets are obligatory for medicines licensed in the European Union and their member states. They are developed according to national guidelines (for medicines licensed in a specific member state) and European guidelines (for medicines licensed in all EU member states). The national guidelines are mainly based on the updated *European Guideline on the readability of the labelling and package leaflet of medicinal products for human use* (2009) used for the marketing authorization procedures. The use of this guideline is not obligatory, but strongly recommended as only patient information leaflets consistent in form and content ensure that the medicine is used correctly. The European Medicines Agency has also designed a set of user-friendly design templates<sup>1</sup> for patient information leaflets, which is published by the Quality Review of Documents (QRD) group. This so-called QRD-template, which is available for public download in all European languages from the European Medicines Agency website, consists of the following rubric headings:

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<sup>1</sup> Different templates are available: one for the central procedure (CP), one for the mutual recognition procedure (MRP), and another one for the decentralised procedure (DP).

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1. What X is and what it is used for
2. What you need to know before you <take> <use>
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

These standard headings are annotated with instructions for leaflet writers/translators concerning the type of information that needs to be placed under the various headings and how the information should be formulated. The following example taken from the European Medicines Agency website provides an illustration:

### 4. *Possible side effects*

*<Additional side effects in children <and adolescents>>*

*[For ALL medicinal products: The new sub-heading should appear at the end of the section 4]*

### *Reporting of side effects*

*If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via the internet at {insert link to the relevant 'national reporting system website' - details will be defined at national level}; or you can report via {insert alternative ways of reporting - details will be defined at national level}. By reporting side effects you can help provide more information on the safety of this medicine.*

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As mentioned above, patient information leaflets should follow the structure and the standard headings of the QRD template and comply with formal requirements such as short sentences (no more than 15 to 20 words long), question-answer format, small text blocks with bullets or numbers, white space, bold font for highlighting and emphasizing text, numbers as words (from one to nine), font size of at least 12 point, diagrams and pictures for illustrating and enhancing text, etc. At the same time, the register should comply with the type of language patients understand. Patient information leaflets are derived from the so-called Summary of Product Characteristics (SmPC), which represent the scientific description of a medicinal product's properties and the conditions attached to its use, written by and for healthcare professionals. In patient information leaflets, this specialized medical knowledge is summarized, re-organized and re-worded in a patient-friendly way taking specific linguistic requirements into account, such as the use of everyday language and present tense as well as active voice, and the use of personal pronouns such as 'we' and 'you', thus creating a sense of inclusion and trust. In addition, patient information leaflets should explain medical terminology, motivate instructions and ensure that the information is consistent and reinforces information already received by patients, etc. Finally the leaflets should avoid jargon and acronyms.

In the present paper we focus on the text segments (so-called rubrics) of the headings 2 and 4 ("What you need to know before you <take> <use>" and "Possible side effects"), which are most relevant in the context of uncertainty avoidance. As already noticed by Paracelsus about 500 years ago, the effect of medicines is inherently associated with potential side effects, and most patients are aware of this fact. Therefore, it is interesting to investigate how information on side effects and warnings are expressed linguistically in patient information leaflets.

### Corpus description

For this pilot study we explored uncertainty avoidance from a contrastive perspective. We used a parallel corpus in English and German which we took from the multilingual database of the European Medicines Agency (EMA). This database is publicly available and provides the patient information leaflets of all medicines authorized in the European Union. As mentioned above, patient information leaflets are part of the Summary of Product Characteristics (SmPC), the document that prepares the marketing authorization of medicines in the European Union. SmPCs (and hence patient information leaflets) are written in English. After approval these documents are translated into the official European languages and thus represent a multilingual corpus in the narrow sense (containing more than three languages; cf. McEnerey and Xiao 2007: 2). The corpus under investigation represents a bilingual translation corpus in which the German corpus (L2) is the translation of the English source texts (L1). As such this corpus type belongs to the category of so-called uni-directional parallel corpora (cf. McEnerey and Xiao 2007: 2). As to the type of texts both SmPCs and patient information leaflets can be specified as factual and instructive texts (cf. Mentrup 1982: 9; Berg-Schmitt 2003), which belong to the domain of external communication.<sup>2</sup> The aim of these texts is to transfer specialized knowledge to non-specialists (patients) in order to inform, instruct and warn. As the use of medicines is part of everyday life patient information leaflets represent quite a familiar genre, which has high relevance for public health, however, as incorrect or misleading information may have severe consequences for patients.

We analysed the text segments of headings 2 (*What you need to know before you <take> <use>* ) and 4 (*Possible side effects*) from ten patient information leaflets in two languages, five in English (source language) and five in German, with a total 11,859 words.

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<sup>2</sup> Sometimes patient information leaflets also represent technical texts, e.g. in the case of innovative medicines such as inhalation devices.

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These specific sections are particularly suitable for a contrastive study into the linguistic expression of uncertainty avoidance, as side effects of approved medicines do not have general validity, i.e. they only apply to certain cases, types of patients, situations, etc. The selected patient information leaflets accompany medicines used to treat hypertension and insomnia and are designed according to the latest update of the European guideline of 2009 (cf. Table 1).

The rationale behind this selection is that both hypertension (high blood pressure) and insomnia, together with anxiety disorders are very common diseases, which affect a large proportion of the adult population. This is the reason why medication for the treatment of these conditions accounts for a major share on the European drug market. As with all medicines the substances used in these medicines can cause a number of undesired side effects. There is, for example, a good chance that one will become dependent on zaleplon (a so-called Z drug, which acts in a similar way as benzodiazepines) if a sleeping tablet such as *Sonata* is taken for more than four weeks. Or drugs to lower increased blood pressure containing telmisartan, for example, can cause serious (possibly fatal) harm to an unborn baby if used during pregnancy. Consequently, warnings and information on possible risks associated with these kinds of drugs are highly relevant, and represent key information in the leaflets, which come with these drugs.

### **Theoretical background and analytical framework**

#### **Uncertainty Avoidance**

The concept of Uncertainty Avoidance (UA) is one of five dimensions which were identified by Hofstede (2001) as a result of a study into the social and psychological value differences which rule thought and behaviour in 72 different countries. Uncertainty



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Avoidance (UA) is defined as ‘the extent to which the members of a culture feel threatened by uncertain or unknown situations’ (Hofstede, 2001, p. 161). Hofstede quantified the level of stress in a society with respect to unknown situations or an unknown future, as well as the other cultural dimensions, using statistical analysis, thus providing evidence for national and cultural differences and similarities. In a general sense Hofstede identifies three general domains directly related to Uncertainty Avoidance through which societies try to ‘control’ the future, to a greater or a lesser extent. These are the domains of technology, law and religion. “Technology” relates to all human artifacts, creating a defense against uncertainties caused by nature, “law” relates to all formal and informal rules guiding social behaviour, creating a defense against the unpredictable behaviour of others, and “religion” relates to everything that is known about the unknown, helping us to accept the uncertainties against which we cannot defend ourselves. The Uncertainty Avoidance Index (UAI), which indicates the extent to which societies try to control the future and their degree of intolerance of ambiguity is calculated on the basis of mean scores regarding the answers to questions probing into rule orientation, employment stability and stress. For the current study into UA in patient information leaflets adherence to rules and stress levels in patients represent relevant elements with regard to their interpretation of the patient information leaflets and their behaviour in taking the medicines in an appropriate and effective way. Notably rule orientation is an important value for our analysis; it may be compared to the role and style of legislation in low- versus high-UAI societies, where the former have few and general laws and the latter many and precise laws (cf. Hofstede, 2001, pp. 169-170 and 180-181 for key differences between low- and high-UAI societies).

Hofstede stresses that uncertainty avoidance is not the same as risk avoidance; uncertainty is to risk as anxiety is to fear (2001). Both fear and risk have a specific focus: for fear it is an object, for risk it is an event. Risk is often expressed using a certain percentage of

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probability. Anxiety and uncertainty are more feeling-like, they lack a specific focus. Anxiety has no clearly determined object, and uncertainty cannot be expressed in terms of probability. Societies that aim to avoid uncertainty do not aim to avoid risk; rather they try to reduce ambiguity, so that events become more predictable and better understandable. For the linguistic analysis of the current study the notions of ambiguity, predictability and clarity are especially relevant as markers of uncertainty avoidance, in order to control patients' interpretation and behaviour .

The uncertainty avoidances indices revealed by Hofstede (2001) for the United Kingdom and Germany are respectively 35 and 65, showing markedly greater uncertainty avoidance in Germany. The current study aims to investigate whether these deviating values are reflected in the German translations of patient information leaflets written in English for the European Medicines Association (EMA), and whether these translations of health communication materials represent culture-specific, convincing target texts for patients taking their medicines. In the following sections linguistic parameters for the degree of uncertainty will be presented. These parameters constitute our analytical framework for comparing uncertainty avoidance in the English source text leaflets and their German translations (cf. Figure 1).

### **Linguistic Parameters of Uncertainty Avoidance: modality**

The concept of uncertainty is expressed logically by the linguistic category of modality. Notably epistemic modality, or 'modalization' in Halliday's terminology, as the category expressing degrees of probability of the 'indicative' type in statements, covering the realm of possible degrees of certainty between 'it is' and 'it isn't' (Halliday, 1994, p. 357) applies to the level of detail and nuance with which patient information leaflet readers are

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informed. But also degrees of modality of the ‘imperative’ type or ‘modulation’ in Halliday’s terminology, i.e. obligation and permission, more generally referred to as ‘deontic’ modality, apply to uncertainty avoidance in patient information leaflets, as these leaflets also have as an objective to shape patients’ actual behaviour when taking the medicines. We will use the terms epistemic and deontic modality henceforth, as they are most commonly used in linguistic analysis, but we refer to Halliday’s interpretative subclassification for analytical purposes below. Expressions of both types of modality contribute to the patient information leaflet as a source of information for the patient on the one hand (epistemic modality) and instruction on the other (deontic modality). In order to assess the degree and type of shifts which may result from the translation process we have distinguished three ‘values’ (strengths) and the implicit versus explicit as well as subjective versus objective orientations, following Halliday (1994). The respective low, median and high values of probability may be paraphrased by the respective adjectives possible – probable – certain, but are also expressed by other modal expressions (modal auxiliaries and other expressions), as may be seen in Table 2, showing the different possible ‘orientations’.

As transpires from the above examples in Table 2, the subjective orientation reflects the sender’s personal position, as opposed to the objective orientation, which (is intended to) reflect (more) generally accepted truths and instructions. In their explicit renderings these subjective versus objective orientations are typically expressed by respectively phrases containing the first personal pronoun *I* on the one hand and by impersonal *it is*-constructions on the other. Example (1) from our corpus similarly uses an explicit objective deontic *it is*-construction; the value is median. Example (2) uses an implicit subjective deontic phrase to instruct the reader. Note, however, that whereas example (3) similarly uses the implicit subjective modal auxiliary *should* with median value, this introduces an objectifying passive clause, contrary to the second personal pronoun reference in example (2); the latter results in a

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much more direct instruction for the individual patient / reader. The instruction in example (4) by means of the imperative mood transmits subjective deontic modality with a high value.

- (1) It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.
- (2) You should not take methylphenidate on the day of your surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.
- (3) Grapefruit and grapefruit juice should not be consumed by people who are taking Exforge. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Exforge.
- (4) Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Examples (1) to (4) above illustrate possible deontic renderings, as displayed in the corpus of patient information leaflets for the current study. In sentence (5) the information on the possible side effect of somnambulism is conveyed as an unlikely possibility by means of the double epistemic markers with an epistemic projecting clause (There is a chance) modifying the epistemic modal *may*, thus lowering the value of this epistemic modification further, so that this case was classified as epistemic with low value; the *there is*-construction objectifies the epistemic modification, so that this case was classified as objective.

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- (5) There is a chance that you may experience somnambulism (sleepwalking), including eating or driving while not fully awake with no memory of the event.

### **Linguistic Parameters of Uncertainty Avoidance: non-modal categories**

In addition to modal expressions our pilot study also revealed other linguistic markers of uncertainty avoidance. These are related respectively to the deontic modal expressions instructing patients on the one hand, and to the informative function modified by epistemic modals on the other. These additional parameters, which provided us with a more comprehensive theoretical framework for assessing uncertainty avoidance, were also partly inspired by Clerehan et al.'s (2005) study of a set of Australian patient information leaflets. Clerehan et al. (2005) aimed to develop a framework based on linguistic theory for analyzing written patient information which moves beyond the former traditional statistical readability estimates using typically average sentence length and average number of words of three or more syllables. Instead they propose a model which is based on a systemic-functional linguistic framework and which starts from the interaction between text and context as the means by which readers construct meanings. This implies an approach which includes a broader set of parameters to evaluate comprehension and communicative effectiveness than that of readability formulae. Clerehan et al.'s parameters start from Swales' (1990) move structure in genre analysis, where each 'move' in the patient information leaflet is related to the reader in terms of a specific function (e.g. to inform or instruct the reader). Thus Clerehan et al.'s model recognizes organization or structure of the text as an important parameter for reader comprehension, as well as the use of headings and visual aspects. But also the 'role-relationships' that are expressed in the text play an important part, notably in patient

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behaviour. These role-relationships refer to “language features in text [which] may indicate the author’s assumptions about the relative status of writer and reader (e.g. expert to lay person)” (2005, p. 337). Clerehan et al. relate this to different styles, such as assertive, directive, conciliatory or collaborative types of language use, or more/less personal styles. Further parameters are metadiscourse, which explains the text’s purpose to the reader and validity of the factual content, which may refer to the source of information and indicate the strength of scientific evidence. Finally, Clerehan et al.’s framework also includes lexical criteria, viz. in terms of the technicality of the vocabulary on the one hand, and information density measured as the average number of content words per clause. Clerehan et al. used these categories to formulate recommendations for effective written healthcare materials in their area.

Inspired by Clerehan et al.’s reference to role-relationships and directive language, we recognized the authors’ ‘rhetorical function’ of an instruction as a part of the category of deontic modality in our framework. Notably with reference to authors’ assumptions about the relative status of writer and reader this includes in our corpus analysis also frequent explicit instructions for the (lay) reader / patient to contact the (specialist) doctor or pharmacist, as in example (6) below.

- (6) If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

Apart from instructions to contact the specialist (doctor or pharmacist), we also found frequent assertions where responsibility is outsourced from the patient information leaflet to either the external specialist, or to the patients themselves. We have labelled these with the abbreviation ERRO for External Role Relation, and added the respective directions in which

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responsibility was shifted or outsourced as either ERRO:  $P \rightarrow S$  or ERRO:  $S \rightarrow P$ . Sentence (1) above, copied here as (7) contains an example of the role relation where responsibility is outsourced from the patient information leaflet to the external (i.e. not part of the leaflet or its authors) specialist, viz. ERRO:  $P \rightarrow S$ . Especially the last sentence, referring to the doctor's potential decision not to start the medicine before additional testing, shifts the main responsibility from the patient information leaflet and the patient's own behaviour to the external specialist. Example (8) illustrates the external role relation which shifts the responsibility to the patient.

(7) It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

(8) ... you may like to ask your doctor for something to help relieve any signs or symptoms.

As indicated above, the parameters of uncertainty avoidance we discovered, in addition to expressions of modality, may be seen to be related to the deontic realm of instructions for patients on the one hand, and to the epistemic realm modifying the way in which patients are informed on the other. With relation to the epistemic domain, we did not only find indications of probability regarding the information which is provided to the patient (cf. example (5) above), but also frequent 'explicit uncertainty markers' (EUMs) relating to the patients assessment or knowledge, as in sentence (6) above, copied here as example (9), which contains the explicit uncertainty marker (EUM) 'If you are in any doubt'.

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- (9) If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

A further category which is markedly present in the patient information leaflets of our corpus is that of 'explicitation'. This includes rephrasing. A subset of this category is that of causal explicitation, typically following an instruction, thus clarifying for the readers why they should follow the instructions. Such causal explicitation may be implicit or explicit.

Sentences (2), (3) and (4) above all contain examples of causal explicitation following an instruction. In (2) and (3) we see explicit causal explicitation, introduced by the phrase This is because .... In the English version of sentence (4), copied here as example (10) the causal explicitation is implicit but this was made explicit in the German translation with the causal conjunction *weil* (*weil Alkohol die Nebenwirkungen dieses Arzneimittels verschlimmern kann*). Example (10) does not only contain causal explicitation of the instruction, but the author aims to exclude any mishaps by adding an explicitation about alcohol as well.

- (10) Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Apart from the modal and related categories of our analytical framework described above, four other parameters are directly related to the above categories, but have not yet been included in our current analysis. Three of these are related to categories distinguished by Clerehan et al. (cf. above). Two are directly related to epistemic modality.



### Results and Discussion

In this section we will first discuss the general results for the English patient information leaflets and their German translations reflecting the parameters of uncertainty avoidance of our analytical framework. We will also comment on some translation shifts. The current section will be concluded with an observation on translation practice and quality in the patient information leaflets of our corpus, which contains implications for readers of translated healthcare information in a broader sense.

With respect to epistemic modality the corpus data show on the one hand almost exclusively median values, with very similar frequencies for both the English and the German patient information leaflets (cf. Table 3), but predominantly high values for deontic modality in both language data (Table 5). Thus it appears that when the PIL-authors and translators convey and modify factual information to the patient concerning the potential occurrence of certain (side) effects, in order to reduce any uncertainty in this respect, they do so with neutral value. The median epistemic modal expressions in both the English and the German corpus sections are predominantly of the subjective type, however, reflecting the specialized authors' professional authority in the matter (cf. Table 4). In examples (2) and (3) above the causal explicitations contain median epistemic modal expressions in the typical context following an instruction or precaution ("This is because there is a chance of a sudden rise in blood pressure during the operation" / "This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine"<sup>3</sup>). In most cases we found correspondence between the English and the translated German epistemic modal expressions, as in examples (11a) and (11b), which are both introduced as objective epistemic expressions.

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<sup>3</sup> The modal auxiliary *can* in this sentence (*can lead to an increase in the blood levels of ...*) might also be classified as a 'dynamic' modal of possibility. In the current study, however, similar cases which modify factual content (as opposed to the deontic (instructive) modal expressions of our analytical framework) have been classified together with the factual modifications of purely epistemic modals.

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Apart from such epistemic correspondences, we also found some correspondences on a different linguistic level which represent instances of very close, literal translations from the English source texts, resulting in rather unidiomatic German phrases, as in examples (12a) and (12b). But even the translation of epistemic modality in 11b) (*besteht die Möglichkeit, dass* ) is rather unidiomatic in German, as a result of literal translation. German renderings with a modal auxiliary (*kann, könnte*) or an adjectival construction (*ist es möglich, dass*) represent more idiomatic constructions.

Apart from the above close, and rather unidiomatic, translations, we also noticed some translations shifts on the epistemic modal level in a few cases, as is the case in examples (13a) and 13(b), where the value of the subjective modal auxiliary *may* is lowered by adding the modal adverb *möglicherweise* to the modal auxiliary in the German translation.

- (11a) If you are taking any medicines belonging to the sleep inducing group, including Sonata, there is a possibility that you may become dependent on them.
- (11b) Wenn Sie Medikamente einnehmen, die einschließlich Sonata zur Gruppe der Schlafmittel gehören, besteht die Möglichkeit, dass Sie von diesen abhängig werden können.
- (12a) Dizziness has been reported.
- (12b) Schwindel wurde berichtet.<sup>4</sup>
- (13a) The following side effects have been observed with the components telmisartan or amlodipine and may occur also with Onduarp: ...

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<sup>4</sup> A more idiomatic translation is “Es wurde über Schwindel berichtet“.

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- (13b) Die folgenden Nebenwirkungen wurden bei den Einzelbestandteilen Telmisartan oder Amlodipin beobachtet und können möglicherweise auch als Nebenwirkungen unter Onduarp auftreten: ...

As indicated above, the deontic modal expressions in the corpus show predominantly high values for both language data (cf. Table 5). In this way readers receive strong instructions, thus reducing any chances of unwanted outcomes when patients take their medicines. Again, the authors' subjective position of relative professional authority is reflected in the use of predominantly subjective modals for both languages (cf. Table 6).

When we look at the most explicit parameter for uncertainty avoidance from our framework, viz. that of Explicit Uncertainty markers (EUMs), we see a much greater representation in the German translated patient information leaflets than in the English original versions, with more than double the number of cases in the German translations (cf. Table 7). Examples (14a) and (14b) illustrate this inequivalence, which is brought about by the added explicitation in the German translation *bzw. Ihr Kind* ('respectively your child').

- (14a) Do not drink alcohol while taking this medicine. ...

- (14b) Sie bzw. Ihr Kind dürfen während der Einnahme dieses Arzneimittels keinen Alkohol trinken, ...

Explicitation as part of the translation shift from English to German in the form of explicit uncertainty markers shows greater uncertainty avoidance in the German leaflets, as expected, following Hofstede's respective values for uncertainty avoidance in the UK (35) and Germany (65) respectively.

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The related parameter of causal explicitation confirms the same tendency for greater explicitation, hence uncertainty avoidance, in German. But although there is overall much more causal explicitation in the German patient information leaflets, the English leaflets have a greater proportion of explicit cases of causal explicitation, whereas the predominance of German causal explicitation in the corpus is of the implicit type (cf. Table 8).

Finally, the avoidance of uncertain or unwanted results where responsibility is shifted from the patient information leaflet authors to either external specialists (ERRO:  $P \rightarrow S$ ) or to the patients/readers themselves (ERRO:  $S \rightarrow P$ ) shows quasi identical findings for both the original English patient information leaflets of the corpus and their German translations (cf. Table 9). As may be expected, the authors mostly shift responsibility to other medical specialists, i.e. as an External Role Relation with the direction  $P \rightarrow S$  (ERRO:  $P \rightarrow S$ ), rather than appealing to the patient directly to take action to contact an external specialist (ERRO:  $S \rightarrow P$ ).

### Conclusions and further research

In conclusion for the values that we have registered for the various parameters of uncertainty avoidance in the English patient information leaflet source texts and their German translations, we notice mainly very similar frequencies for most categories. However, the parameters of Explicit Uncertainty Markers (EUMs) and implicit causal explicitation are markedly more frequent in the German translated texts than in the English source texts, showing greater uncertainty avoidance in the German patient information leaflets. Following Hofstede's (2001) values for uncertainty avoidance in the UK and in Germany (respectively 35 and 65), this finding confirms our expectations. But apart from the correspondences and the deviating values for EUMs and causal explicitation we also noticed some instances of literal translations from the English source texts, resulting in unidiomatic German phrases, as

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indicated above (cf. examples (12a) and (12b)). Such unidiomatic target phrases, resulting from literal translation practice, feed the assumption that the corresponding English and German patient information leaflet frequencies for most parameters of uncertainty avoidance in our analysis might also partly be due to literal translation practice. In this way they are not necessarily full reflections of national or cultural values of uncertainty avoidance as defined by Hofstede, but perhaps only to a certain extent so. And, while the UK and Germany both represent Western cultures, it may be assumed that the implication of unidiomaticity resulting from close translation practice, might well have more severe implications for translations of healthcare communication materials between more diverse source and target cultures, such as those of Western and Arab areas, for instance. This hypothesis, which is based on the results of a qualitative exploratory pilot study, must be confirmed by subsequent quantitative research of a representative corpus.

In view of the findings pointing to partly unidiomatic target texts resulting from close translation practice, further research may include finding new methods for mapping unidiomaticity in target texts. This may be considered systematically on different linguistic levels, including the parameters discussed above, as well as other linguistic levels. Such a systematic consideration of literal translation practice on one or more linguistic levels may then lead to recommendations for translators of health communication materials, or indeed other types of text.

One linguistic level which certainly deserves further study for the benefit of health communication readers' comprehension and response is the field of terminology. Various formats are used in patient information leaflets for the indication of specialized medical terms. These include different combinations and orders of lay terms, specialized terms and explicitations of (specialized) medical terms. Again, this may lead to further recommendations for the preferred terminological format on a European or broader level.

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The terminological formats, as well as the parameters of uncertainty avoidance discussed above may be the object of surveys probing more directly into readers' response to those categories with respect to the experienced factuality and usefulness of the information on the one hand and the clarity of instructions on the other in patient information leaflets or health communication texts in general.

Finally, our study has focussed on indicators of the effectiveness of a culture-specific index, viz that of uncertainty avoidance in translated materials, which represent large proportion of materials for daily life usage. But a study probing into culture-specific indices as indicators of national or area-related characters only could complement our analysis on the basis of a contrastive corpus which consists of primary, untranslated texts. In this respect close collaboration with pharmaceutical enterprises producing patient information leaflets in the original language (German or other languages) designed for national drug markets would be very fruitful.

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## Tables

Table 1: Corpus design

Name	Active substance	Therapeutic area	Last update	German corpus n words	English corpus n words
Adcirca	Tadalafil	Hypertension	25/03/2013	917	894
Circadin	Melatonin	Sleep Initiation and Maintenance Disorders	24/04/2013	927	929
Exforge	amlodipine / valsartan	Hypertension	05/08/2010	1,506	1,608
Onduarp	telmisartan / amlodipine besilate	Hypertension	10/08/2012	1,354	1,522
Sonata	Zaleplon	Sleep Initiation and Maintenance Disorders	01/03/2012	1,100	1,102
				5804	6055

Table 2: Examples of type and orientation of modality (adapted from Halliday, 1994, p. 358).

	Subjective: explicit	Subjective: implicit	Objective: explicit	Objective: explicit
Epistemic <sup>5</sup>	I think [in my opinion] Mary knows	Mary will / 'll know	Mary probably knows	It's likely that Mary knows
Deontic	I want John to go	John should go	John's supposed to go	It's expected that John goes

<sup>5</sup> The epistemic and deontic types of modality are labelled 'Modalization : probability' and 'Modulation : obligation' respectively by Halliday. As explained above, this paper uses the terms 'epistemic' and 'deontic' since these are more generally used and recognized in linguistics.

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Table 3: High, median and low values of epistemic modality in the corpus

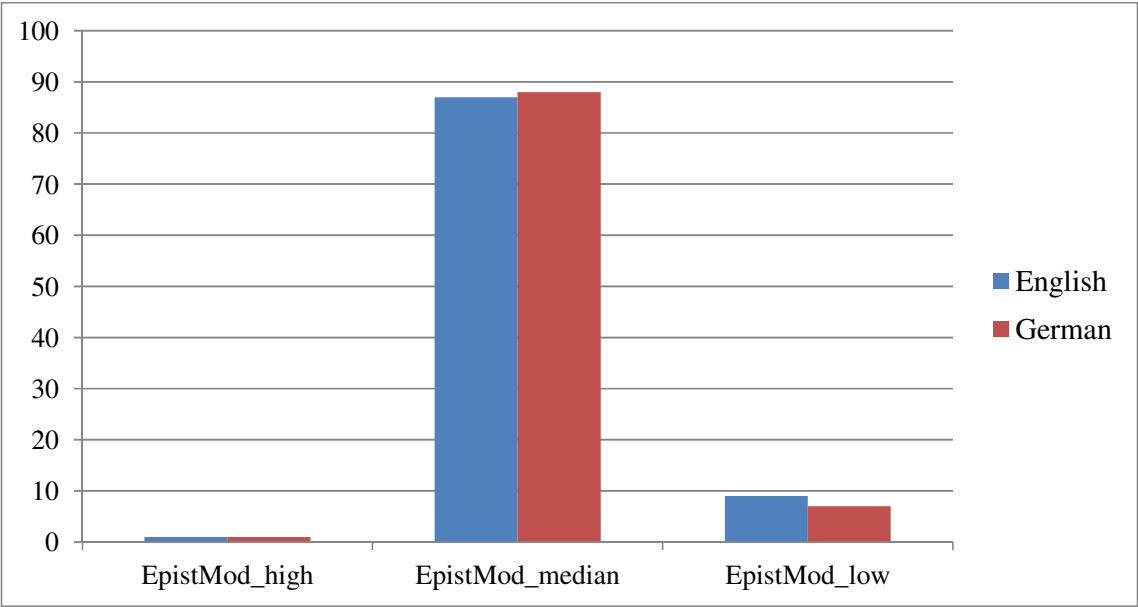
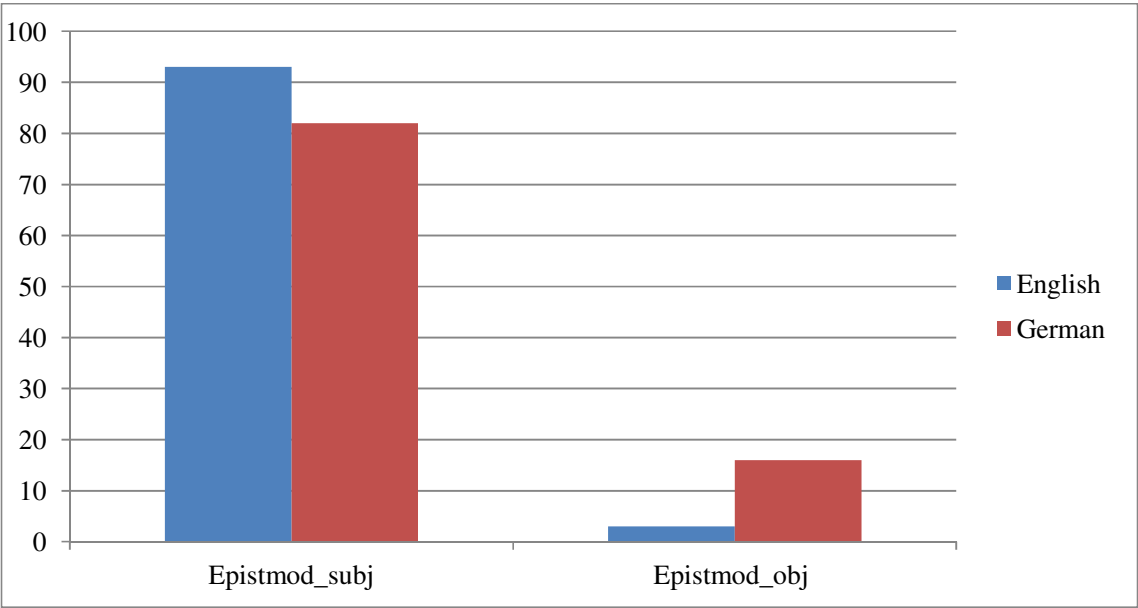


Table 4: Subjective vs. objective orientations of epistemic modality in the corpus



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Table 5: High , median and low values of deontic modality in the corpus

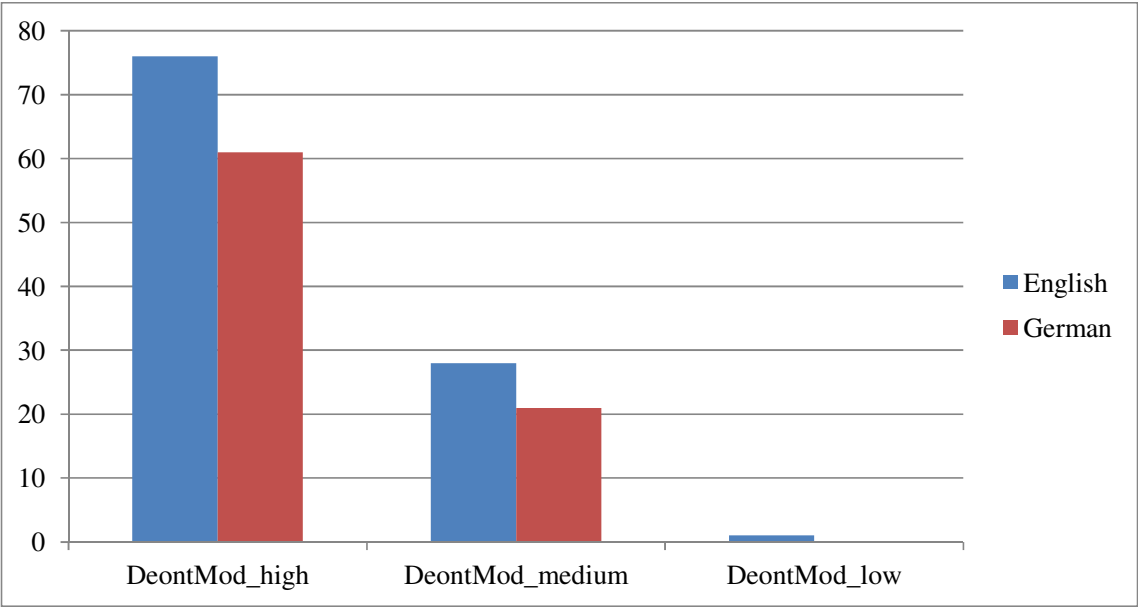
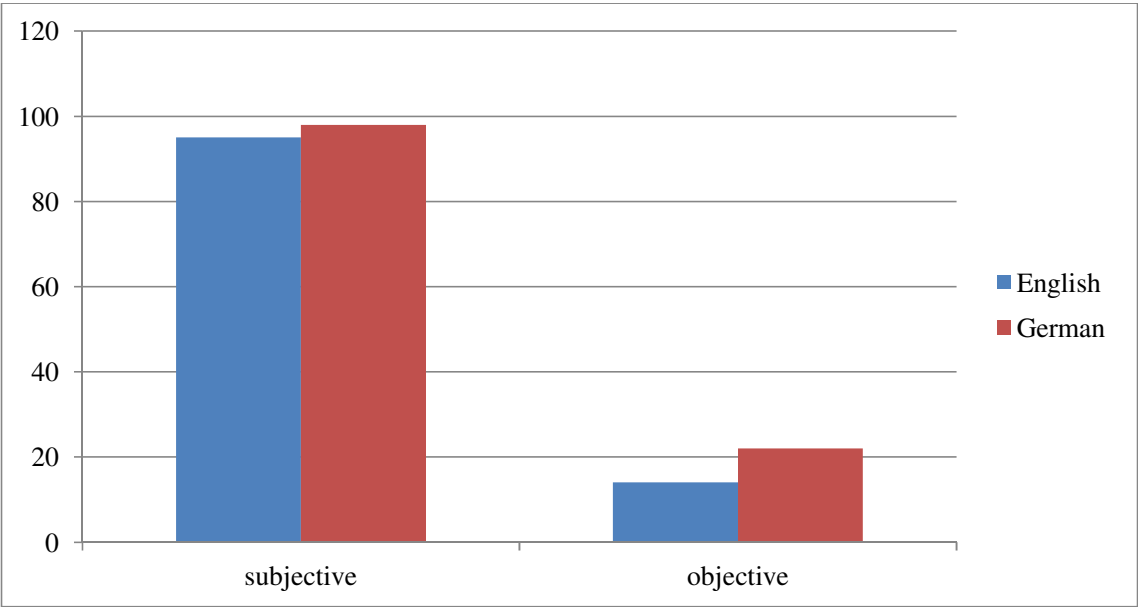


Table 6: Subjective vs. objective orientations of deontic modality in the corpus



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Table 7: Explicit uncertainty markers in the corpus (EUMs)

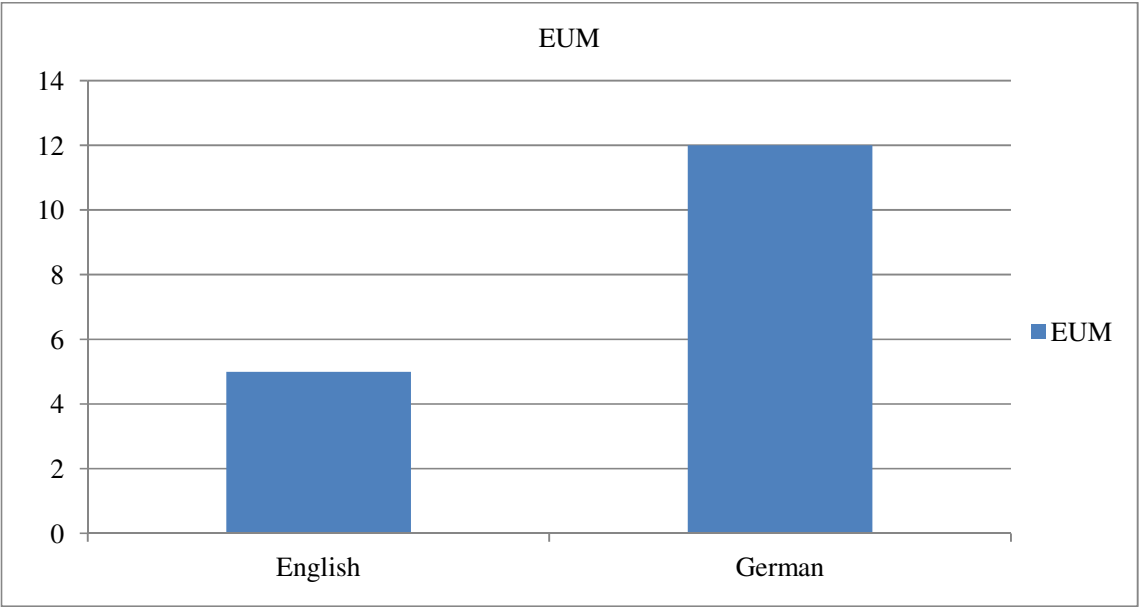


Table 8: Implicit and explicit causal explication in the corpus

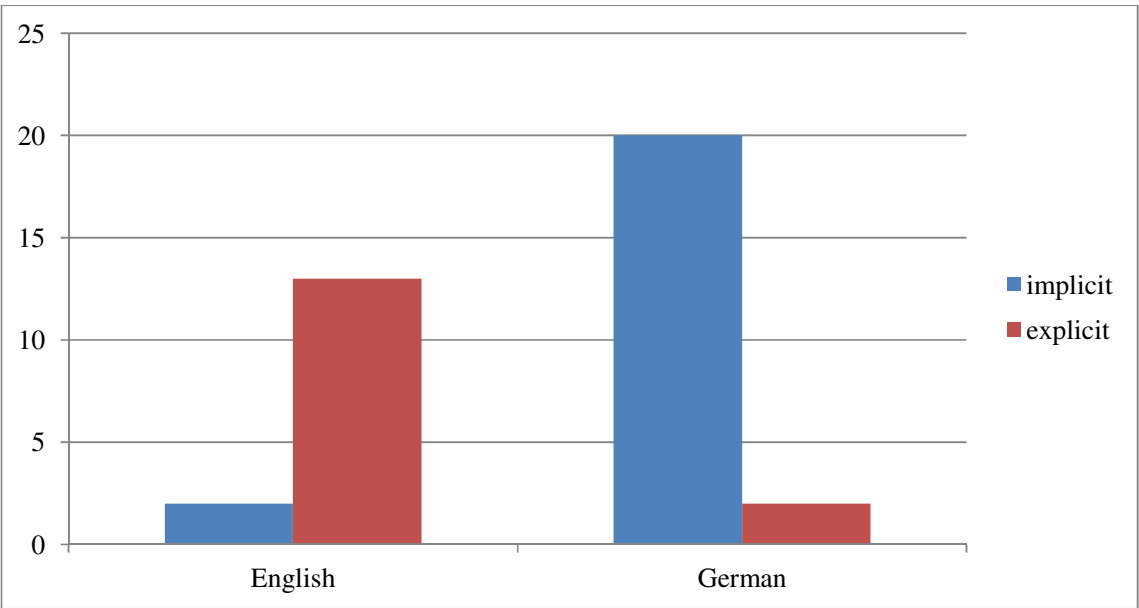
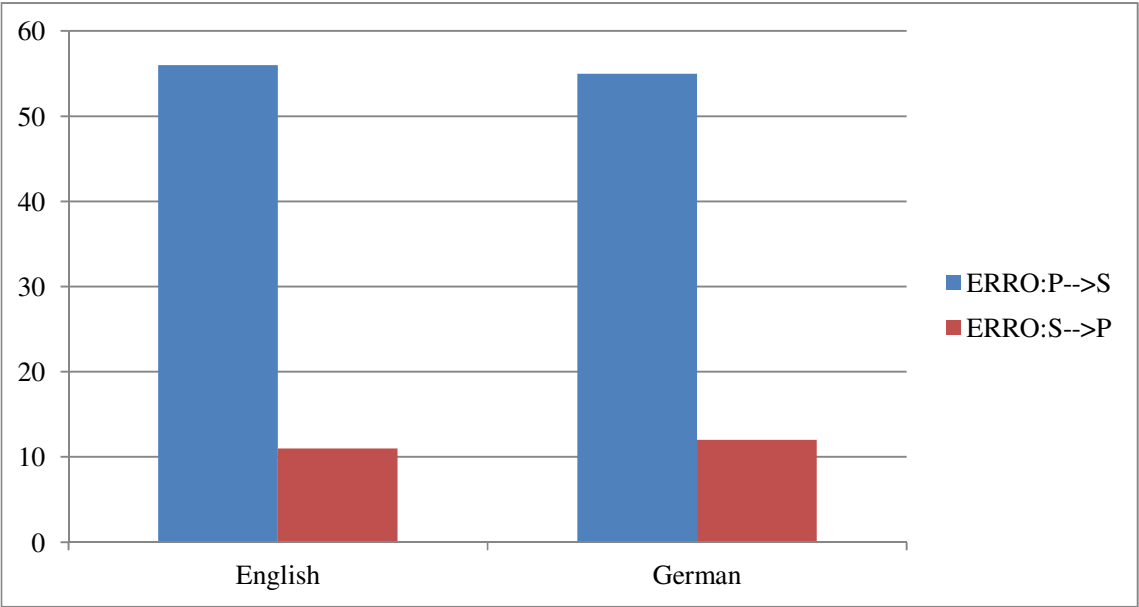


Table 9: External role-relations in the corpus (ERRO)



Figures

Figure 1: Analytical framework for Uncertainty Avoidance in a corpus of English and German patient information leaflets.

Epistemic modal expressions (subjective/objective, explicit/implicit)
Deontic modal expressions (incl. instructions) (subjective/objective, explicit/implicit)
(External Role Relation) ERRO: $P \rightarrow S$ or $S \rightarrow P$
Explicit Uncertainty Markers (EUMs)
Explicitation
Causal explicitation (explicit/implicit)